

Akebia Therapeutics 245 First Street, Suite 1400 Cambridge, MA 02142

617.871.2098 Akebia.com

#### **FOIA Confidential Treatment Request**

The entity requesting confidential treatment is: Akebia Therapeutics, Inc. 245 First Street Cambridge, MA 02142 Attn: Jason A. Amello 617-871-2098

November 5, 2019

#### **VIA EDGAR**

Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attention: Mr. Jacob Luxenburg

Ms. Angela Connell

Re: SEC Comment Letter

dated September 25, 2019 Akebia Therapeutics, Inc.

Form 10-K for the Fiscal Year Ended December 31, 2018 (filed March 26, 2019) Form 10-Q for the Quarterly Period Ended June 30, 2019 (filed August 8, 2019)

File No. 001-36352

Set forth below is the response of Akebia Therapeutics, Inc. (the "Company") to the above-referenced comment letter sent to Jason A. Amello, the Company's Senior Vice President, Chief Financial Officer and Treasurer.

# Form 10-Q for the Quarterly Period Ended June 30, 2019

# **Item 1. Legal Proceedings**

# <u>Legal Proceedings Relating to Auryxia – ANDA</u> <u>Litigation, page 60</u>

Comment No. 1: Please tell us how you considered the results of the ANDA litigation, which was settled prior to the issuance of your most recent Form 10-Q and could potentially negatively impact future sales of Auryxia, in assessing your goodwill and intangible assets (including your developed product rights for Auryxia) for potential impairment as of the period ended June 30, 2019.

#### Response to Comment No. 1

As of the date of the Company's merger (the "Merger") with Keryx Biopharmaceuticals, Inc. ("Keryx") on December 12, 2018 (the "Merger Date"), Keryx held 14 patents covering Auryxia® (ferric citrate), with expiration dates ranging from 2020 through 2030.¹ Based on the available information at the time of the Merger, including the expiration dates for the patents, and through consultation with patent counsel, we estimated that the patent exclusivity period for Auryxia would extend through [\*\*]. There have not been any changes in patent expiration dates from the date of the Merger through the filing date of the Company's 10-Q for the quarter ended June 30, 2019.

As of the Merger Date, we allocated the purchase price to the intangible asset for the fair value of our developed product rights for Auryxia (the "Auryxia Intangible Asset"). [\*\*].

On August 2, 2019, Keryx (now a subsidiary of the Company) and Panion & BF Biotech, Inc. ("Panion") entered into a settlement and license agreement (the "License Agreement") with Par Pharmaceutical, Inc. ("Par") resolving patent litigation brought by Keryx and Panion in response to Par's Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Auryxia tablets prior to the expiration of the applicable patents. Pursuant to the terms of the settlement, Keryx and Panion will grant Par a license to market a generic version of Auryxia in the United States beginning on March 20, 2025 (subject to FDA approval), or earlier under certain circumstances customary for settlement agreements of this nature. Prior to the filing of our Form 10-Q for the quarterly period ended June 30, 2019, we considered what impact, if any, the License Agreement had on the Auryxia Intangible Asset. [\*\*].

Akebia Therapeutics, Inc. respectfully requests that the information contained in Response #1 be treated as confidential information and that the Commission provide timely notice to Akebia Therapeutics, Inc., Jason A. Amello, Senior Vice President, Chief Financial Officer and Treasurer, 245 First Street, Cambridge, MA 02142, phone 617-871-2098, before it permits any disclosure of the bracketed information contained in Request #1.

During the second quarter of 2019, we also evaluated whether there were any indicators of impairment of goodwill at the reporting unit. Consistent with our assessment at year-end, we concluded that we continue to operate in one operating segment which we consider to be our only reporting unit. Our evaluation of indicators of impairment of goodwill included our assessment of the following factors:

- the Company's market capitalization as of June 30, 2019 was greater than the carrying value of our reporting unit;
- the Company continued to project positive future cash flows; and
- our conclusion that the Auryxia Intangible Asset was not impaired.

As a result of this evaluation, we did not identify any indicators of impairment for goodwill during the six-months ended June 30, 2019 at the reporting unit.

Please contact me at (617) 871-2087 if you have any questions regarding this response to the Staff comment letter.

Sincerely,

/s/ Jason A. Amello

Jason A. Amello

Senior Vice President, Chief Financial Officer and Treasurer

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Following the date of the Merger, one additional patent covering Auryxia was issued.